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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Basil D. Favis

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EXAMINER

BARHAM, BETHANY P

ART UNIT

PAPER NUMBER

1615

NOTIFICATION DATE

DELIVERY MODE

06/22/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/552,357	<b>Applicant(s)</b> FAVIS ET AL.	
	<b>Examiner</b> BETHANY BARHAM	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11/07/08.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 6-12, 14-36, 38, 40 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 13, 37, 39 and 41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/3/05, 2/9/07</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Summary***

Receipt of IDS's filed on 10/3/05 and 2/9/07 are acknowledged. Applicant's response filed on 11/7/08 is also acknowledged. Claims 1-42 are pending. Claims 1-5, 13, 37, 39 and 41 are rejected.

### **Election/Restrictions**

Applicant's election of Group I in the reply filed on 11/7/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is still deemed proper and is therefore made FINAL.

## **OBJECTIONS**

Claims 37, 39, and 41 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Currently only claims 1-5 and 13 are pending but claims 37, 39 and 41 state "any of claims 1-13" which is improper.

## **NEW REJECTIONS**

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 37, 39, and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 37, 39, and 41 provides for the use of a microporous biodegradable article, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 37, 39, and 41 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

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**DOUBLE PATENTING**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 13, 37, 39 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 19, 26, 28, 30 of copending Application No. 12/093712. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a porous material comprising essentially continuous pore network for use as tissue engineering, controlled release, and implantable medical devices.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 13, 37 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Washburn et al (cited in IDS and ISR).

The instant claims are drawn to a microporous biodegradable polymeric article comprising an essentially continuous porosity with a void volume from 10 to 90%, wherein pore diameters show a unimodal distribution set to a predefined unimodal peak location corresponding to a chosen pore diameter, and wherein a majority of pores has a diameter within +/- 50% of the chosen pore diameter.

- Washburn et al teaches porous scaffolds for tissue engineering using poly(caprolactone) with poly(ethylene oxide) results in continuous networks of polymer and void spaces, a pore size of 20-150 or 10-100 microns and 70% or 50% voids (abstract, pg. 25 col. 1, and pg. 26 col. 1, Figure 5) (meeting the limitations of claims 1-2 and 13). Note MPEP 2113 states "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself" thus the product limitation claim 13 is met by Washburn et al.

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- Figure 5 teaches void space with 50 micron size (meeting the limitations of claims 3-4).
- Tissue engineering and implants are taught as uses for the porous scaffolds of Washburn et al (abstract, pg. 20) (meeting the limitations of claims 37 and 41).

Claims 1-5, 13, 37, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by 5,856,367 ('367) (cited in IDS).

- '367 claims a biocompatible porous matrix (such as PLGA) with a network of interconnecting pores and a void volume of 20-97% and pore diameters of 0.5-50 microns (claims 1-7, Example 6) (meeting the limitations of claims 1-5 and 13). Note MPEP 2113 states "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself" thus the product limitation claim 13 is met by '367.
- '367 teaches tissue regeneration and medical implants (col. 5, lines 10-35) (meeting the limitations of claims 37 and 41).

Claims 1-5, 13, 37, 39 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by 6,281,257 ('257) (cited in 892).

- '257 claims a biocompatible porous matrix (such as PLGA) with a network of interconnecting pores and a void volume of at least 80% and pore diameters of 50-200 microns (abstract; col. 2, lines 20; col. 8, lines 19-20) (meeting the limitations of claims 1-5 and 13). Note MPEP 2113 states "[E]ven though

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product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself" thus the product limitation claim 13 is met by '257.

- '257 teaches tissue regeneration, platforms, matrices and medical implants (col. 1, lines 10-45) (meeting the limitations of claims 37, 39 and 41).

Claims 1-4, 13, 37, 39 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by 2002/0005600 ('600) (cited in 892).

- '600 claims a biocompatible porous matrix (such as PLGA) with a network of interconnecting pores and a void volume of at least 80% and pore diameters of 100-500 microns (claims 42-43 and abstract; [0002, 0064, 0091]; Fig. 6) (meeting the limitations of claims 1-4 and 13). Note MPEP 2113 states "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself" thus the product limitation claim 13 is met by '600.
- '600 teaches tissue regeneration, controlled release and medical implants (abstract, col. 1, lines 10-45) (meeting the limitations of claims 37, 39 and 41).

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)-272-



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6175. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bethany Barham  
Art Unit 1615

/Tracy Vivlemore/  
Primary Examiner, Art Unit 1635